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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/836,348	04/18/2001	William A. Koehring	N1239-009	8755

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EXAMINER

IBRAHIM, MEDINA AHMED

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 01/02/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/836,348

Applicant(s)

KOEHRING, WILLIAM A.

Examiner

Medina A Ibrahim

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 07 October 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-17, 19, 26, 27 and 30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 1-5, 7 and 10 is/are allowed.
- 6) ☐ Claim(s) 6, 8-17, 19, 26, 27 and 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 5) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 6) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Applicant's response filed 07/22/02 in reply to the Office action mailed 10/07/02 has been entered. Claims 18, 20-25, 28-29 and 31-33 have been cancelled. Therefore, Claims 1-17, 19, 26-27, and 30 are pending and are under examination.

This Office action contains NEW GROUNDS OF REJECTION not necessitated by Applicants' amendments. Therefore, this action is non-final. The delay in applying these new grounds of rejection is regretted.

All objections and rejections not stated below have been withdrawn. The objection to the claims and to the specification for failing to recite ATCC accession number have been withdrawn in view of Applicants' statement that the deposit ATCC accession number will be provided upon allowance of the claims.

Claim Rejections - 35 USC § 112, 2nd

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6, 8-11, 13-14, 16, 27 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 6, the metes and bounds of a "genetic factor" is unclear.

Claim 8 is indefinite because "cells or tissue culture of regenerable cells" lacks proper antecedent basis. It is suggested that the "cells or tissue culture of regenerable cells being from a tissue" be replaced with ---wherein the tissue is---.

In claim 9, "capable of expressing" implies the plant may or may not express all the morphological and physiological characteristics of the inbred line RAA1. It is suggested that "capable of expressing" be replaced with --- has ---.

In claim 11, " second said parent" should be changed to --- said second inbred parent---, for proper dependency.

Claim 17 is indefinite for failing to recite the steps for identifying the inbred parent plants.

Claim 19 remains rejected as the metes and bounds of what is retained in "RAA1-derived" corn plants or progeny are unclear. Applicants' amendment to the claim does not obviate the rejection because the amended claim recites "RAA1-derived" corn plant or progeny. Also, in part (b), " MNI1-derived" should be replaced with ---RAA1-derived---.

Claim 30 remains rejected because of the recitation of "using" without any positive method steps by which one could practice the claimed method. Applicant has amended the claim, however, the amendment does not obviate the rejection. The only possible method steps, "using", employing", and "obtaining" are not definite method steps, and it is not clear if any are intended to be method steps and/or if they are intended to be consecutive method steps in the same process.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6, 17, 26-27 and 30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to a corn plant or parts thereof of the inbred corn line RAA1 which have been transformed so that its genetic material contains one or more transgenes operably linked to one or more regulatory elements, and a method for producing a corn plant that contains said transgenes by crossing the transformed plant of the inbred line RAA1 with a non-transformed RAA1 plant or with another corn line. Corn plants and parts thereof produced by said method are also claimed.

Applicant has not disclosed or provided guidance for a transformed or non-transformed inbred corn line RAA1 or parts thereof comprising one or more transgenes, wherein said genes are transferred by breeding techniques. No guidance has been provided for the obtention of corn plants comprising in its genome a transgene from transformed parent plants. In addition, no guidance has been provided for the introgression of any trait from a multitude of non-disclosed and uncharacterized parentals into the claimed variety, wherein said introgression should result in successful expression of the desired trait but should not interfere with expression of the remaining traits whose combination confers patentability to the instantly exemplified variety, and which introgression should not introduce unwanted linked genetic material into the exemplified cultivar which would disrupt its patentably unique genetic complement. The prior art does not amend the deficiency. In addition, Applicant has not provided

Art Unit: 1638

guidance regarding the genetic or the morphological characteristics of any of the breeding partners, or the resultant progeny.

While transformation of plants with a specific transgene for a desired trait by genetic engineering may be within the level of one skilled in the art, the state of the art teaches that it is unpredictable whether a gene or genes for conferring a phenotype in one plant genetic background may be transferred into the genetic background of another plant to confer the phenotype in said different plant. For example, Hunsperger et al (US Patent No. 5, 523, 520) disclosed a specific gene trait in the genetic background of one plant which has been introgressed into the genetic background of another plant of the same species, that didn't result in the expected transfer gene trait (column 3, lines 26-46). Kraft et al teach that linkage disequilibrium effects and linkage drag prevent the making of plants comprising a single transferred trait, and such that effects are unpredictably genotype specific and loci dependent in nature. Kraft et al teach that linkage disequilibrium is created in breeding materials when several lines become fixed for a given set of alleles at a number of different loci, and that very little is known about the plant breeding material, and therefore, is an unpredictable effect in plant breeding (page 323, column 1, line 7 to line 15). See, Eshed et al teach that in plants, epistatic genetic interactions from the various genetic components comprising contributions from different genomes may affect quantitative traits in a genetically complex and less than additive fashion (page 1815, column 1, line 1 to page 1816, column 1, line 1). Neither the instant specification nor the prior art provides evidence that such linkage disequilibrium, linkage drag, or epistatic effect are not common in corn

Art Unit: 1638

breeding materials, such that one or more transgenes can be transferred from one genetic background to another.

In addition, the specification does not provide specific guidance for how the transgene is introduced in the plant. The state of the art teaches unpredictability inherent in the transformation of plants to obtain desired phenotype. For example, see Napoli et al (The Plant Cell, Vol. 2, pp. 279-289, 1990) who teach the introduction of a transgene (chalcone synthase) into a plant that did not result in the expected desired trait in the plant (see page 279, Abstract). Therefore, absent specific guidance, one skilled in the art is left with trial and error experimentations considered to be undue.

Claim 17 is included in the rejection because Applicant has not disclosed or provided guidance for how to identify the claimed inbred from a collection of other plants or a repeatable process to reproduce the claimed seed. In fact, it is for that reason that deposit of the claimed line is required to enable the invention. Therefore, one skilled in the art would not be able to practice the claimed method without undue experimentation.

Therefore, given the lack of guidance in Applicants' specification regarding transfer of genes by backcrossing in Applicant's corn line, the lack of guidance regarding the isolation of a multitude of non-exemplified transgenes or their evaluation in particular corn genetic background, the state of the art, the unpredictability inherent in single gene transfer, and lack of working examples, one skilled in the art would not be able to make and/or use the invention, without undue experimentations.

Written Description

Claims 11-16, 19, 26-27 and 30 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reasons of record as set forth in the last Office action mailed 07/09/02. Applicant's arguments filed 10/7/02 have been fully considered but are not deemed persuasive.

1. Claims 11 is included in the rejection because the claim is not limited a method for producing F1 hybrid plants. The claim encompasses a method for producing other hybrid plants. Claims 26-27 are included in the rejection because Applicant has not described a multitude of non-exemplified transgenes or their phenotypic effects in particular corn genetic background. In addition, the claims do not characterize the sequence or identity of the transgenes or recite phenotypic effects (claim 27). Because various breeding techniques (claim 30) and a number of uncharacterized breeding partners and breeding generations have been employed, substantial variation in structure and phenotypes are expected among the resultant plants. Therefore, the disclosure of a single inbred corn line RAA1 would not provide adequate written description for all hybrid plants including F1 generation and other hybrid plants and subsequent generation plants or method for using F1 plants to produce subsequent generation plants, absent more. Accordingly, written description requirement is not satisfied.

Applicants argue that once inbred RAA1 is developed a skilled breeder can cross the inbred RAA1 with any other corn genotype to produce a hybrid corn plant having 50% of its germplasm from RAA1 and these hybrid can be self pollinated to produce F2. Applicants also argue that Tables 1-3 of the specification shows data on several hybrid combinations of RAA1 compared to other hybrid corn hybrids. Therefore, Applicants urge that the rejection be withdrawn (response, pages 5-6).

Examiner maintains that the rejection is proper given that the claimed hybrid plants and seeds and a method for producing other than F1 hybrid plants are not described in the specification. While a skilled breeder knows how to cross inbred RAA1 plant with another corn plant to produce a hybrid plant having 50% of its germplasm from RAA1, a skilled breeder cannot predictably determine the phenotype of the resultant hybrid will be wherein 50% of its germplasm is unknown. There is no written description of the second 50% of the germplasm of the claimed hybrid plants, since the second parent involved in the crossing has not been described.

Regarding Tables 1-3, it is noted that the disclosed hybrid plants are only plants of the F1 generation and are only described by some physiological characteristics such as percent root or percent stalk lodge, moisture or yield. Such physiological characteristics are insufficient to provide identifying characteristics that distinguish the claimed hybrid plant from other hybrid plants. In addition, the claims are not limited to F1 generation plants but encompass other hybrids. Further, the limitations in Tables 1-3 are not recited in the rejected claims. Therefore, Applicants arguments are not found persuasive. Therefore, the rejection is maintained.

Claim Rejections - 35 USC § 102/103

Claims 11-16, 19 and 30 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bergemann (US Pat. 5,633,429, filed December 1997).

The claims are drawn to hybrid corn plants/seeds including F1 hybrid plants as well as other hybrid plants produced by crossing the inbred corn line RAA1 with plants of another corn line and a method for using said plants/seeds to produce further subsequent generation plants. The claims are also drawn to various breeding techniques used to generate hybrid plants/seeds.

Bergemann teaches inbred corn line designated as LH227 and a method for producing hybrid plants and seeds by crossing a plant of the inbred corn line LH227 with plants of another corn line as well as F1 hybrid and subsequent generation plants. The reference teaches breeding methods such as pedigree and recurrent selection breeding methods and backcrossing to transfer specific desirable trait between plants. The corn plants of the instant invention and those of the prior art share agronomic characteristics such as leaf color that is medium greenish, dark anthocyanin of brace roots, light green fresh husk, distinct kernel rows, yellow hard endosperm, red cob, stay green (7) and resistance to diseases (see at least columns 4-7). Since Applicant has not disclosed specific morphological and physiological characteristics for the claimed hybrid plants /seeds, the claimed plants are expected to be indistinguishable from those of the prior art, especially since the second parent plants involved in the crossing are unknown. The Examiner does not have sufficient facts to determine whether the corn

Art Unit: 1638

plant and seeds are inherently the same and cannot conclude that the claimed subject matter would have been obvious since it cannot be determined whether the corn plants differ. Where the prior art product seems to be identical, except that the prior art is silent to a characteristic or property claimed, then the burden shifts to Applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention. See *In re Best* 195 USPQ 430, 433 (CCPA 1977).

Remarks

Claims 1-10, 17, 26-27 are free of the prior art of record.

Claims 1-5, 7 and 10 are allowable.

Papers related to this application may be submitted to Technology Sector 1 by facsimile transmission. Papers should be faxed to Crystal Mall 1, Art Unit 1638, using fax number (703) 308-4242. All Technology Sector 1 fax machines are available to receive transmission 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Medina A. Ibrahim whose telephone number is (703) 306-5822. The Examiner can normally be reached Monday-Thursday from 8:30AM to 5:30PM and every other Friday 9:00AM to 5:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Amy Nelson, can be reached at (703) 306-3218.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

10/8/02

Mai



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